

**Data Evaluation Record on the Acute Toxicity of NAK 4455 (Transfluthrin) to Fish
(*Leuciscus idus melanotus*)**

PMRA Submission Number { }

EPA MRID Number 49617830

Data Requirement:

PMRA Data Code	{ }
EPA DP Barcode	436376
OECD Data Point	{ }
EPA MRID	49617830
EPA Guideline	850.1075

Test material: NAK 4455

Purity: 94.5%

Common name: Transfluthrin


Chemical name: IUPAC: 2,3,5,6-Tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate

CAS name: (2,3,5,6-Tetrafluorophenyl)methyl (1R,3S)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate

CAS No.: 118712-89-3

Synonyms: Bayothrin

Primary Reviewer: Mary Samuel
Environmental Scientist, CDM/CSS-Dynamac JV


Signature: 
Date: 01/09/17

Secondary Reviewer: Elizabeth Krupka
Environmental Scientist, CDM/CSS-Dynamac JV V

Signature: 
Date: 2/7/2017

Primary Reviewer: Frank T. Farruggia, Ph.D.
Senior Scientist, EPA/OPP/EFED/ERB1

Date: 9/5/17

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Secondary Reviewer(s): { }
{EPA/OECD/PMRA}

Date: { }

Reference/Submission No.: { }

Company Code { } [For PMRA]
Active Code { } [For PMRA]
Use Site Category: { } [For PMRA]
EPA PC Code 129140

Date Evaluation Completed: 05-09-2017

CITATION: Grau, R. 1988. Acute Toxicity of NAK 4455 Golden Orfe (*Leuciscus idus melanotus*) in a Flow-Through-Test. Unpublished study performed by Bayer AG, CE Research, Institute of Ecobiology, Crop Protection Center Monheim, D-5090 Leverkusen, Germany. Report No. F0-1108. Study No. E 2830103-7. Study sponsored by Bayer AG, Crop Protection Center Monheim, D-5090 Leverkusen, Germany. Study initiated March 21, 1988 and completed October 06, 1988.

This Data Evaluation Record may have been altered by the Environmental Fate and Effects Division subsequent to signing by CDM/CSS-Dynamac JV personnel.

DISCLAIMER: This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the acute toxicity of a pesticide to fish. It is not intended to prescribe conditions to any external party for conducting this study nor to establish absolute criteria

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regarding the assessment of whether the study is scientifically sound and whether the study satisfies any applicable data requirements. Reviewers are expected to review and to determine for each study, on a case-by-case basis, whether it is scientifically sound and provides sufficient information to satisfy applicable data requirements. Studies that fail to meet any of the conditions may be accepted, if appropriate; similarly, studies that meet all of the conditions may be rejected, if appropriate. In sum, the reviewer is to take into account the totality of factors related to the test methodology and results in determining the acceptability of the study.

EXECUTIVE SUMMARY:

In a 96-hour acute toxicity study, Golden Orfe (*Leuciscus idus melanotus*) were exposed to **NAK 4455** at nominal concentrations of 0 (negative and solvent controls), 0.50, 0.89, 1.58, 2.81, and 5.00 µg ai/L under flow-through conditions. Mean-measured concentrations were 0 (control), 0.34, 0.72, 1.47, 2.50, and 3.71 µg ai/L.

Mortalities were not observed in the negative and solvent controls or in the mean-measured 0.34 and 0.72 µg ai/L treatment groups. At 96 hours, mortalities were 100%, 90%, and 100% in the mean-measured 1.47, 2.50, and 3.71 µg ai/L treatment groups, respectively. The 96-hour LC₅₀ was derived using the mean-measured test concentrations was 1.09 µg/L. The dose response is steep in this study, 100% mortality at 1.47 ug a.i./L and zero mortality at 0.72 ug a.i./L.

Sublethal effects were observed in the 1.47, 2.50, and 3.71 µg ai/L treatment groups. Sublethal effects included fish swimming on side and/or inverted, swimming behavior slightly irregular and red marks on the skin.

Based on the results of this study, **NAK 4455** would be classified as **very highly toxic** to *Leuciscus idus melanotus* in accordance with the classification system of the U.S. EPA.

This study is **scientifically sound** and is classified as **supplemental (quantitative)**. The study was downgraded because the test species is not one of the recommended species as listed in the 850.1075 guideline.

Results Synopsis

Test Organism Size/Age (mean weight or length): weight: 3.5 ± 0.5 g; length 7.2 ± 0.3 cm; Age: not reported.

Test Type (Flow-through, Static, Static Renewal): Flow-through

LC₅₀: 1.09 µg ai/L 95% C.I.: 0.98 to 1.21 µg ai/L

Probit Slope: N/A* 95% C.I.: N/A

*The dose response is steep in this study, 100% mortality at 1.47 ug a.i./L and zero mortality at 0.72 ug a.i./L.

Endpoint(s) Affected: Mortality and sub-lethal effects including fish swimming on side and/or inverted, swimming behavior slightly irregular and red marks on the skin.

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(*Leuciscus idus melanotus*)**

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study was conducted according to the guidelines “EEC Directive 79/831, Annex V, Methods for Determination of Ecotoxicity, Method 5.1.1. Acute Toxicity for Fish (which complied with the U.S. EPA Ecological Effects Test Guideline OCSPP 850.1075, Fish Acute Toxicity Test, Freshwater and Marine) and OECD Guidelines for Testing of Chemicals, Guideline No. 203: Fish, Acute Toxicity Test. The following deviations were noted:

1. The test species is not one of the recommended species listed in the 850.1075 guideline.
2. The particulate matter of the dilution water were not reported.
3. Results from the periodic screening analysis of the dilution water were not reported.
3. Analytical measurements of the active ingredient were done at 0, 24, 48 and 96 hours in the concentrations 0.50, 0.89 and 2.81 ug/l. The concentrations 1.58 and 5.00 ug/l were only analyzed at 0 and 24 hours.
4. The study was conducted with one replicate per test concentration; two replicates per test concentration are preferred.

These deviations do impact the acceptability of the study.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. This study was conducted in compliance with the U.S. EPA Good Laboratory Practice Standards (GLP), 40 CFR Parts 160 and 792 (1983), which are compatible with the OECD Principles of GLP.

A. MATERIALS:

1. Test material NAK 4455

Description: Brown solid

Batch No. : Mixed pt. 250987

Purity: 94.5%

Stability of compound under test conditions: The compound remained stable under test conditions. Recovery ranged from 89-135% of nominal concentrations at 24 hours and 101-128% of nominal concentrations at 96 hours.

Storage conditions of test chemicals: At room temperature.

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Physicochemical properties of NAK 4455.

Parameter	Values	Comments
Water solubility at 20°C	Not reported	
Vapor pressure	Not reported	
UV absorption	Not reported	
pKa	Not reported	
Kow	Not reported	

(OECD recommends water solubility, stability in water and light, pKa, Pow, vapor pressure of test compound)

2. Test organism:

Species: Golden Orfe (*Leuciscus idus melanotus*)

Age at test initiation: Not reported

Weight at study initiation: 3.5 ± 0.5 g

Length at study initiation: 7.2 ± 0.3 cm

Source: Fischzucht EGGERS, D-2354 Hohenwestedt, Federal Republic of Germany.

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding Study: A range-finding study was not conducted.

b. Definitive Study

Table 1: Experimental Parameters

Parameter	Details	Remarks
		Criteria
<u>Acclimation</u>		
Period:	At least 14 days.	The recommended acclimation period is a minimum of 14 days; OECD guideline recommends a minimum of 12 days. Pretest mortality should be <3% 48 h. prior to testing. OECD pretest mortality criteria: >10% = rejection of entire batch; ≥5 and ≤10% = continued acclimation for 7 days; <5% = acceptable.
Conditions: (same as test or not)	Same as test (dilution water and temperature).	
Feeding:	Fish were fed with a commercial trout diet. Fish were not fed 48 hours prior to the test.	
Health: (any mortality observed)	Not reported.	

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Parameter	Details	Remarks
		Criteria
Duration of the test	96 hours	<i>The recommended test duration is 96 hours.</i>
<u>Test condition</u>		
Static/flow-through	Flow-through	<i>A reproducible supply of toxicant is recommended. Consistent flow rate is usually 5-10 vol/24 hours; meter systems should be calibrated before and after study and checked twice daily during test period.</i>
Type of dilution system - for flow-through method.	Water flow was controlled by a flow meter at rate of 25 ± 1 litre/hour.	
Renewal rate for static renewal	N/A	
Aeration, if any	No aeration was provided.	
		<i>Aeration is not recommended; OECD guideline recommends aeration. If aeration is necessary, test solutions must be analyzed periodically to verify exposure.</i>
<u>Test vessel</u>		
Material: (glass/stainless steel)	Aquaria (material not specified).	<i>Test vessel size is usually 19 L (5 gal) or 30 x 60 x 30 cm. Fill volume is usually 15-30 L of solution.</i>
Size:	100 L	
Fill volume:	Not reported	
Source of dilution water Quality:	Dilution water was reconstituted water aerated to saturation with ionic concentrations of calcium, magnesium, sodium, potassium, chlorine, carbonate and sulphate. The dilution water is analyzed in intervals ca. 6 months for contaminants.	<i>Recommended source of dilution water is soft, reconstituted water or water from a natural source. EPA does not recommend the use of dechlorinated tap water; however, its use may be supportable if the biological responses for the organisms and chemical analyses of residual chlorine meet conditions in the Agency's 850.1010 guidelines for dilution water (http://www.epa.gov/opptsfrs/OPPTS_Harmonized/850_Ecological_Effects_Test_Guidelines/Draft/850.1010.pdf) Dilution water should be intensely aerated before the study. OECD permits dechlorinated tap water.</i>

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Parameter	Details	Remarks
		Criteria
Biomass loading rate	Not reported	<i>Recommended static conditions are <0.8 g/L at <17°C and <0.5 g/L at >17°C. Recommended flow-through conditions are <1 g/L/day. OECD recommends a maximum of 1 g fish/L for static and semi-static, while higher rates are recommended for flow-through.</i>
<u>Test concentrations:</u> nominal: measured:	0 (negative and solvent controls), 0.50, 0.89, 1.58, 2.81, and 5.00 µg ai/L 0 (control), 0.34, 0.72, 1.47, 2.50, and 3.71 µg ai/L	
Solvent (type, percentage, if used)	Acetone 0.1 ml/L	<i>The solvent should not exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests; OECD recommends that the solvent not exceed 100 mg/L.</i>
Lighting	16 hours light and 8 hours dark photoperiod.	<i>The recommended photo period is 16 hours of light and 8 hours of dark with a 15-30 minute transition period. OECD recommends a photo period of 12-16 hours.</i>
Feeding	Fish were not fed during the test.	<i>Fish should not feed during the study.</i>
<u>Recovery of chemical</u> Frequency of determination Level of quantitation Level of detection	Recovery ranged from 89-135% of nominal concentrations at 24 hours and 101-128% of nominal concentrations at 96 hours. Samples were collected at 0, 24, 48, and 96 hours and analyzed via GC with EC detection. Not reported Not reported	
Positive control {if used, indicate the chemical and concentrations}	N/A	

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Parameter	Details	Remarks
		Criteria
Other parameters, if any	None	

2. Observations:

Table 2: Observations

Parameter	Details	Remarks
		Criteria
Parameters measured including the sublethal effects/toxicity symptoms	Mortality Sublethal effects	
Observation intervals	0, 4, 24, 48, 72 and 96 hours	
		<i>Observation intervals should be a minimum of every 24 hours.</i>
Were raw data included?	Yes	
Other observations, if any	None	

II. RESULTS AND DISCUSSION:

A. MORTALITY:

There was no mortality in the negative and solvent controls or in the nominal 0.50 and 0.89 µg ai/L treatment groups. At 96 hours, mortalities were 100%, 90%, and 100% in the nominal 1.58, 2.81, and 5.00 µg ai/L treatment groups, respectively. The LC₅₀ value was reported to be 1.25 µg ai/L using the nominal concentrations.

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Table 3: Effect of NAK 4455 on Mortality of Golden Orfe (*Leuciscus idus melanotus*).^a

Mean-measured (and nominal) Concentrations (µg ai/L)	No. of fish at start of study	Observation period									
		4 Hrs		24 Hrs		48 Hrs		72 Hrs		96 Hrs	
		No. Dead	% Mortality	No. Dead	% Mortality	No. Dead	% Mortality	No. Dead	% Mortality	No. Dead	% Mortality
0 (Negative Control)	10	0	0	0	0	0	0	0	0	0	0
Solvent control	10	0	0	0	0	0	0	0	0	0	0
0.34 (0.50)	10	0	0	0	0	0	0	0	0	0	0
0.72 (0.89)	10	0	0	0	0	0	0	0	0	0	0
1.47 (1.58)	10	0	0	10	100	10	100	10	100	10	100
2.50 (2.81)	10	0	0	9	90	9	90	9	90	9	90
3.71 (5.00)	10	1	10	10	100	10	100	10	100	10	100
LC ₅₀ (95% CI)	1.25 (1.1 to 1.4) µg/L (based on the nominal concentrations)										

^a Data were obtained from Table 1 on page 11 of the study report.

B. NON-LETHAL TOXICITY ENDPOINTS:

There were no apparent sublethal effects observed in the negative and solvent controls or the nominal 0.50, and 0.89 µg ai/L treatment groups. Sublethal effects were observed in the 1.58, 2.81, and 5.00 µg ai/L treatment groups. Sublethal effects included fish swimming on side and/or inverted, swimming behavior slightly irregular and red marks on the skin.

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Table 4: Sub-lethal Effects of NAK 4455 on Golden Orfe (*Leuciscus idus melanotus*).^a

Mean-measured (and nominal) Concentrations (µg ai/L)	Observation period				
	4 Hrs	24 Hrs	48 Hrs	72 Hrs	96 Hrs
	% affected	% affected	% affected	% affected	% affected
0 (Negative Control)	AN	AN	AN	AN	AN
Solvent control	AN	AN	AN	AN	AN
0.34 (0.50)	AN	AN	AN	AN	AN
0.72 (0.89)	AN	AN	AN	AN	AN
1.47 (1.58)	10 SN, RM	D	D	D	D
2.50 (2.81)	10 IN, RM	1 IN, RM; 9 D	1 IN; 9 D	1 IN; 9 D	1 IN; 9 D
3.71 (5.00)	9 IN, RM; 1 D	D	D	D	D
LC ₅₀ (95% CI)	1.25 (1.1 to 1.4) µg ai/L				

^a Data were obtained from Table 1 on page 11 of the study report.

AN = Appear normal; SN = Swimming behavior slightly irregular, IN = Swimming on side and/or inverted;
RM = Red marks on the skin; D = Dead.

C. REPORTED STATISTICS:

The LC₅₀ values and corresponding 95% confidence intervals were calculated using the method of Thompson and Weil (On the Construction of Tables for Moving Average Interpolation, Biometrics, Vol. 8, pp. 51 - 54, 1952). Where the data were inadequate to use statistical methods the LC₅₀ is given as the geometric mean of the two concentrations and the range between the two respective concentrations is given as 95 %-confidence interval.

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: Mortality data and corresponding mean-measured concentrations were entered into CETIS statistical software version 1.8.7.12 with database backend settings implemented by EFED on 10/20/15. The Untrimmed Spearman-Kärber method was used to estimate the LC₅₀ value and corresponding 95% confidence interval.

LC₅₀: 1.09 µg ai/L 95% C.I.: 0.98 to 1.21 µg ai/L
Probit Slope: N/A 95% C.I.: N/A

E. STUDY DEFICIENCIES:

This study used a species that isn't one of the recommended species in the 850.1075.

F. REVIEWER'S COMMENTS:

The reviewer's results were based on the mean-measured concentrations, whereas the study author based results on the nominal concentrations. The reviewer's results are reported in the Executive Summary and Conclusions

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sections of this DER.

The in-life phase of the definitive test was conducted from March 21 to March 25, 1988.

G. CONCLUSIONS:

This study **is scientifically sound** and is classified as **supplemental (quantitative)**. Mortalities were not observed in the negative and solvent controls or in the mean-measured 0.34 and 0.72 µg ai/L treatment groups. At 96 hours, mortalities were 100%, 90%, and 100% in the 1.47, 2.50, and 3.71 µg ai/L treatment groups, respectively. The 96-hour LC₅₀ was derived using the mean-measured test concentrations was 1.09 µg/L. The dose response is steep in this study, 100% mortality at 1.47 ug a.i./L and zero mortality at 0.72 ug a.i./L.

Sublethal effects were observed in the 1.58, 2.81, and 5.00 µg ai/L treatment groups. Sublethal effects included fish swimming on side and/or inverted, swimming behavior slightly irregular and red marks on the skin.

III. REFERENCES:

Thompson and Weil. 1952. On the Construction of Tables for Moving Average Interpolation, Biometrics, Vol. 8, pp. 51-54.

CETIS Analytical Report

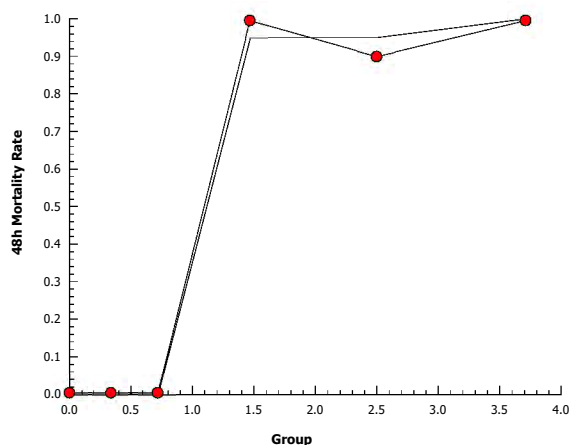
Report Date: 08 Feb-17 06:07 (p 1 of 2)
Test Code: 129140 49617830 | 11-7428-2902

OPPTS 850.1075 Acute Fish			Bayer AG		
Analysis ID:	14-3263-7666	Endpoint:	48h Mortality Rate	CETIS Version:	CETISv1.8.7
Analyzed:	08 Feb-17 5:58	Analysis:	Untrimmed Spearman-Kärber	Official Results:	Yes
Batch ID:	11-8631-8760	Test Type:	Mortality (96-h)	Analyst:	
Start Date:	21 Mar-88	Protocol:	OPPTS 850.1075 Acute Fish	Diluent:	Reconstituted Water
Ending Date:	25 Mar-88	Species:	Leuciscus Idus Melanotus (Golden Orfe)	Brine:	
Duration:	96h	Source:	Fischzucht EGGERS	Age:	

Spearman-Kärber Esti mates							
Threshold Option	Threshold	Trim	Mu	Sigma	LC50	95% LCL	95% UCL
Control Threshold	0	0.00%	0.0359	0.0232	1.09	0.976	1.21

48h Mortality Rate Summary			Calculated Variate(A/B)								
Group	Control Type	Count	Mean	Min	Max	Std Err	Std Dev	CV%	%Effect	A	B
0	Negative Control	1	0	0	0	0	0			0	10
0.34		1	0	0	0	0	0			0	10
0.72		1	0	0	0	0	0			0	10
1.47		1	1	1	1	0	0	0.0%		10	10
2.5		1	0.9	0.9	0.9	0	0	0.0%		9	10
3.71		1	1	1	1	0	0	0.0%		10	10

Graphics



CETIS Analytical Report

Report Date: 08 Feb-17 06:07 (p 2 of 2)
Test Code: 129140 49617830 | 11-7428-2902

OPPTS 850.1075 Acute Fish

Bayer AG

Analysis ID: 04-7548-7761	Endpoint: 96h Mortality Rate	CETIS Version: CETISv1.8.7
Analyzed: 08 Feb-17 5:58	Analysis: Untrimmed Spearman-Kärber	Official Results: Yes
Batch ID: 11-8631-8760	Test Type: Mortality (96-h)	Analyst:
Start Date: 21 Mar-88	Protocol: OPPTS 850.1075 Acute Fish	Diluent: Reconstituted Water
Ending Date: 25 Mar-88	Species: Leuciscus Idus Melanotus (Golden Orfe)	Brine:
Duration: 96h	Source: Fischzucht EGGERS	Age:

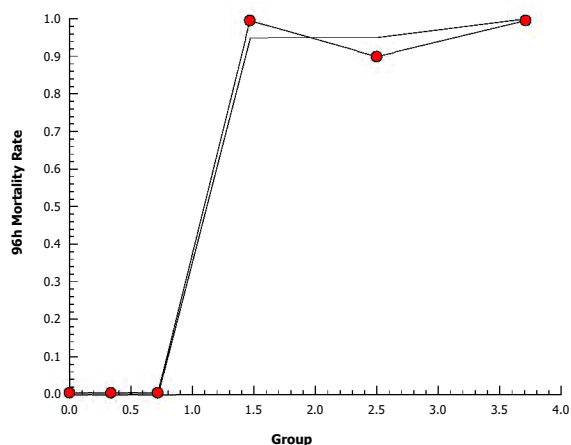
Spearman-Kärber Esti mates

Threshold Option	Threshold	Trim	Mu	Sigma	LC50	95% LCL	95% UCL
Control Threshold	0	0.00%	0.0359	0.0232	1.09	0.976	1.21

96h Mortality Rate Summary

Group	Control Type	Count	Calculated Variate(A/B)							A	B
			Mean	Min	Max	Std Err	Std Dev	CV%	%Effect		
0	Negative Control	1	0	0	0	0	0			0	10
0.34		1	0	0	0	0	0			0	10
0.72		1	0	0	0	0	0			0	10
1.47		1	1	1	1	0	0	0.0%		10	10
2.5		1	0.9	0.9	0.9	0	0	0.0%		9	10
3.71		1	1	1	1	0	0	0.0%		10	10

Graphics



CETIS Summary Report

Report Date: 08 Feb-17 06:08 (p 1 of 1)
 Test Code: 129140 49617830 | 11-7428-2902

OPPTS 850.1075 Acute Fish

Bayer AG

Batch ID:	11-8631-8760	Test Type:	Mortality (96-h)	Analyst:	
Start Date:	21 Mar-88	Protocol:	OPPTS 850.1075 Acute Fish	Diluent:	Reconstituted Water
Ending Date:	25 Mar-88	Species:	Leuciscus Idus Melanotus (Golden Orfe)	Brine:	
Duration:	96h	Source:	Fischzucht EGGERS	Age:	
Sample ID:	07-0252-2932	Code:	49617830	Client:	CDM Smith - E. Krupka
Sample Date:	21 Mar-88	Material:	Transfluthrin	Project:	Insecticide
Receive Date:		Source:	Bayer AG, Crop Protection		
Sample Age:	NA	Station:			
Batch Note: MRID 49617830					
Sample Note: MRID 49617830					

Point Estimate Summary

Analysis ID	Endpoint	Level		95% LCL	95% UCL	TU	Method
14-3263-7666	48h Mortality Rate	LC50	1.09	0.976	1.21		Spearman-Kärber
04-7548-7761	96h Mortality Rate	LC50	1.09	0.976	1.21		Spearman-Kärber

48h Mortality Rate Summary

Group	Control Type	Count	Mean	95% LCL	95% UCL	Min	Max	Std Err	Std Dev	CV%	%Effect
0	Solvent Blank	1	0			0	0	0	0		
0	Negative Control	1	0			0	0	0	0		
0.34		1	0			0	0	0	0		
0.72		1	0			0	0	0	0		
1.47		1	1			1	1	0	0	0.0%	
2.5		1	0.9			0.9	0.9	0	0	0.0%	
3.71		1	1			1	1	0	0	0.0%	

96h Mortality Rate Summary

Group	Control Type	Count	Mean	95% LCL	95% UCL	Min	Max	Std Err	Std Dev	CV%	%Effect
0	Solvent Blank	1	0			0	0	0	0		
0	Negative Control	1	0			0	0	0	0		
0.34		1	0			0	0	0	0		
0.72		1	0			0	0	0	0		
1.47		1	1			1	1	0	0	0.0%	
2.5		1	0.9			0.9	0.9	0	0	0.0%	
3.71		1	1			1	1	0	0	0.0%	

48h Mortality Rate Detail

Group	Control Type	Rep 1
0	Solvent Blank	0
0	Negative Control	0
0.34		0
0.72		0
1.47		1
2.5		0.9
3.71		1

96h Mortality Rate Detail

Group	Control Type	Rep 1
0	Solvent Blank	0
0	Negative Control	0
0.34		0
0.72		0
1.47		1
2.5		0.9
3.71		1